UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, STATE OF ILLINOIS, STATE OF MARYLAND, STATE OF WASHINGTON, Plaintiffs,	
v.	07 Civ. 8621 (PAC)
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendant.	ECF CASE

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS

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PRELIMINARY STATEMENT

This case is brought by several states seeking to challenge recently issued federal policy guidance regarding the State Children's Health Insurance Program ("SCHIP"), a federal matching-grant program that helps states provide health insurance to low-income children. The guidance at issue was disseminated by the Centers for Medicare and Medicaid Services ("CMS") – an agency within the Department of Health and Human Services ("HHS") – in the form of a letter sent by CMS to state health officials on August 17, 2007 (the "SHO Letter"). The letter clarifies how CMS intends to apply long-standing statutory and regulatory requirements designed to ensure that state SCHIP programs focus on serving low-income populations and do not supplant private forms of health insurance. Plaintiffs challenge the issuance of the SHO Letter on both substantive and procedural grounds: they claim that it imposes requirements in excess of CMS's statutory and regulatory authority, and that it was unlawful for CMS to promulgate those requirements without undertaking notice-and-comment rulemaking.

As explained below, plaintiffs' complaint should be dismissed in its entirety for lack of jurisdiction, based on three independent grounds. First, the case is unripe. The SHO Letter is not self-executing and will have no concrete effect on the plaintiffs unless and until it is definitively applied to them through individualized administrative proceedings. In the meantime, judicial review not only is premature, but is impossible in the absence of any administrative record. Postponing review would work no hardship upon plaintiffs, as they face no present dilemma between complying with the SHO Letter and foregoing SCHIP funds.

Second, jurisdiction is precluded by the SCHIP statute's judicial review provisions. Those provisions authorize direct appellate review in federal appeals court of any final agency determination that a state's SCHIP program (or proposed change to the program) violates federal requirements. Plaintiffs may not circumvent this statutory scheme by filing a pre-enforcement

action in district court to enjoin such determinations before they have actually been made. They must follow the exclusive route to judicial review established by Congress.

Third, regardless of whether the SCHIP statute's review scheme is exclusive, it precludes plaintiffs from obtaining review under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701 *et seq*. APA review is available only with respect to agency action "for which there is no other adequate remedy in a court." 5 U.S.C. § 704. It is well established that a statutorily prescribed judicial review mechanism, such as the one prescribed by the SCHIP statute, qualifies as an adequate judicial remedy. Review is thus unavailable to plaintiffs under the APA; and there is no other statute that could waive the government's sovereign immunity with respect to this suit, as is required for this Court to exercise jurisdiction.

Accordingly, the case should be dismissed on jurisdictional grounds. However, were the Court nonetheless to find that it has jurisdiction over any aspect of the case, the only claim it could possibly review in the absence of an administrative record is plaintiffs' procedural claim that the SHO Letter constitutes an unlawful rulemaking. Should the Court reach this claim, it should reject it as a matter of law. The SHO Letter is not tantamount to a binding regulation but is instead merely a "general statement of policy" or "interpretive rule" that announces how the agency intends to apply existing legal requirements. Such policy guidance is specifically exempted from the APA's rulemaking requirements.

BACKGROUND

A. The SCHIP Program

1. Targeted Low-Income Children Served by SCHIP

SCHIP was created by the Balanced Budget Act of 1997, Pub L. 105-33, 111 Stat. 251, under Title XXI of the Social Security Act, 42 U.S.C. § 1397aa, *et seq*. The program makes federal matching funds available to states to help provide health insurance coverage to "uninsured,

low-income children in an effective and efficient manner that is coordinated with other sources of health benefits for children." 42 U.S.C. § 1397aa. Each participating state receives a capped allotment of federal matching funds based on a statutory formula. *See id.* § 1397dd. Within these allotments, the federal government reimburses states for a large percentage of program expenditures, with the federal matching rate varying among states from 65 to 83 percent. *See id.*§ 1397ee; 42 C.F.R. § 457.622. Since the program's inception in 1997, Congress has provided nearly $40 billion for the program.

States have considerable flexibility in designing their SCHIP programs within broad federal guidelines. A state's program may be designed either as an extension of the state's existing Medicaid program or as a separate health insurance program; or the state may combine both options. 42 C.F.R. § 457.70. Each state sets its own eligibility requirements, limits of coverage, premiums and deductibles, and administrative and operating procedures. *Id.* § 457.1.

In order to receive SCHIP funding, however, a state must have in place a "state plan" approved by CMS. *See* 42 U.S.C. § 1397aa(b); 42 C.F.R. § 457.150. The plan must provide a range of information about how the state intends to provide health insurance to targeted low-income children through its SCHIP program. *See* 42 U.S.C. § 1397bb. Among other things, a state's plan must describe the procedures it will use "to ensure . . . that only targeted low-income children are furnished child health assistance" under the plan. *Id*. § 1397bb(b)(3)(A). The statute defines a "targeted low-income child" as a child who is not covered by Medicaid or other form of insurance, and whose "family income" is either (1) at or below 200 percent of the federal poverty level ("FPL") or (2) no more than 50 percentage points higher than the state's Medicaid eligibility threshold in 1997 (which varies among states, ranging generally from 133 to 185 percent of the FPL). *See* 42 U.S.C. § 1397jj(b), (c)(4); 42 C.F.R. § 457.310.

This case arises from the fact that, in practice, an increasing number of states have effectively exceeded these statutory income limits by manipulating the way "family income" is defined under their state plans. The term "family income" is not defined in the SCHIP statute and is only loosely defined in the regulations. *See* 42 C.F.R. § 457.10 (defining the term as "income as determined by the State for a family as defined by the State"). Given this flexibility, a number of states have defined "family income" so as to disregard substantial portions of a family's earnings. If, say, a state disregards earnings equivalent to 100 percent of the FPL, then a child in the state whose family actually earns 300 percent of the FPL would have a "family income" of only 200 percent of the FPL for purposes of the state's plan – and thus would technically qualify as a "targeted low-income child" eligible for SCHIP coverage. In this manner, plaintiff New York, for example, is presently seeking to expand coverage to children with effective family incomes of up to 400 percent of the FPL – equivalent to $84,800 for a family of four, *see* 73 Fed. Reg. 3,971 (Jan. 23, 2008) – by amending its definition of "family income" to exclude income up to 200 percent of the FPL. Currently, at least 17 states employ such "income disregards" so as to extend SCHIP coverage above the levels contemplated on the face of the SCHIP statute.

2. Program Efficiency and Crowd-Out Prevention Requirements

Despite their flexibility in defining income, states remain constrained by the statute's basic mandate that their programs provide health insurance to "uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children." 42 U.S.C. § 1397aa(a); *see also* 42 C.F.R. §§ 457.40, 457.50. The expansion of SCHIP coverage to higher-income populations through "income disregards" threatens the effectiveness and efficiency of SCHIP programs, in that such expansion risks diverting program funds away from maximizing enrollment among lower-income populations in greater need of governmental coverage. Of particular concern, because higher-income populations tend to have

greater access to private forms of health insurance, *e.g.*, through employee benefit programs, extending SCHIP coverage to such populations is more likely to substitute for, or "crowd out," private health insurance. Where such substitution occurs, the SCHIP program fails to serve its fundamental mission of reducing the nation's population of uninsured children; instead, children are merely shifted from private to government insurance rolls.

As noted in the preamble to the SCHIP regulations, providing SCHIP coverage risks supplanting employer-provided or other private insurance because SCHIP coverage often costs less for beneficiaries and provides a broader range of benefits. 66 Fed. Reg. 2,490, 2,602 (Jan. 11, 2001). Thus, the availability of SCHIP coverage can lead parents to decline employer-based health insurance for their children in favor of a higher paycheck. By the same token, employers have an incentive to reduce or eliminate their contributions for coverage of employees' dependents if they can encourage their employees to enroll their children in SCHIP instead. *See id.*; *see also* Congressional Budget Office, The State Children's Health Insurance Program (May 2007) ("CBO Paper") at VIII-IX, available at http://www.cbo.gov/ftpdocs/80xx/doc8092/05-10-SCHIP.pdf. Indeed, on the basis of a review of the research literature, the Congressional Budget Office recently observed that for every 100 children who enroll in SCHIP, there is a corresponding reduction in private coverage of between 25 and 50 children. *Id.* at IX.[1]

[1] The use of limited federal dollars to provide benefits to children who already have access to health insurance not only frustrates the purpose of the program, but ultimately undermines its fiscal viability. In recent years, numerous states have exhausted their SCHIP allotments, requiring federal bailouts, and it is estimated that if current eligibility rules and benefits are unchanged, 43 states will have outstripped their available funds by 2017, in the amount of $8.9 billion. *Id.* at 13. These trends underscore the need to minimize substitution in order to ensure that program funds are effectively spent.

Both Congress and CMS have long been mindful of the risk of such crowd-out. The SCHIP statute specifically requires a state plan to describe how the state will ensure that SCHIP coverage "does not substitute for coverage under group health plans" and is "coordinat[ed] with other public and private programs providing creditable coverage for low-income children." 42 U.S.C. § 1397bb(b)(3)(C)&(E).[2] Likewise, the program's implementing regulations require states to adopt "reasonable procedures" to prevent substitution. 42 C.F.R. § 457.805.

As CMS explained when it originally promulgated this requirement in 2001, the phrase "reasonable procedures" was intended to allow appropriate crowd-out procedures to be developed over time based on "emerging research" and "state experience with substitution." 66 Fed. Reg. at 2,602. CMS stressed, however, that "evidence shows that there is a greater likelihood of substitution at higher income levels." *Id.* at 2,603. Thus, the agency stated that it would adhere to the following general guidelines in applying the "reasonable procedures" requirement: in providing coverage at or below 200% FPL, a state must monitor the occurrence of substitution; if coverage is extended above 200% FPL, the state should identify how it will limit substitution if monitoring efforts show unacceptable levels of substitution; and if coverage is extended above 250% FPL, the state must have specific strategies in place to prevent substitution in addition to monitoring. *Id.* at 2,603.[3] CMS stated that it planned "to work closely with States to develop appropriate substitution strategies," *id.*, and that, if monitoring indicated unacceptable levels of

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[2] The term "group health plans" refers to health insurance provided through employee benefit plans. *See* 42 C.F.R. § 457.10.

[3] For the sake of brevity, this brief will use "250% FPL" and similar shorthand to refer to the effective reach of SCHIP coverage. For example, where the brief refers to extending coverage beyond "250% FPL," the reference is to extending coverage to children whose effective family incomes (*i.e.*, without factoring in state "income disregards") exceed 250 percent of the FPL.

substitution, CMS "may reconsider the requirements intended to prevent substitution of coverage," *id.* at 2,604.

3. CMS's Recent Policy Guidance Announced in the SHO Letter

On August 17, 2007, CMS sent a letter to state health officials elaborating upon the guidance it had provided in 2001. *See* Am. Compl., Ex. B ("SHO Letter"). The SHO Letter clarifies how CMS intends, going forward, to apply "existing statutory and regulatory requirements in reviewing State requests to extend eligibility under [SCHIP] to children in families with effective family income levels above 250 percent of the [FPL]." *Id.* at 1. The letter explains that, "[a]s CMS has developed more experience and information from the operation of SCHIP programs, it has become clear that the potential for crowd-out is greater for higher income beneficiaries." *Id.*; *see also* CBO Paper at IX. The letter further notes that, when CMS originally issued the program regulations, the agency indicated that it would require states to identify specific crowd-out strategies in their state plans if they opted to extend coverage above 250% FPL, and that, over time, states have developed the following five strategies in response:

- requiring higher-income beneficiaries to share the costs of SCHIP coverage (through deductibles, premiums, *etc*.) at a level approximating the cost-sharing imposed by competing private plans;

- barring individuals from switching to SCHIP from private coverage unless they have been without private insurance for a number of months ("uninsurance periods");

- monitoring health insurance status at the time of application, to ensure that applicants are not presently insured;

- verifying family insurance status through insurance databases; and

- preventing employers from changing dependent coverage policies in a manner tending to shift dependents to public coverage.

SHO Letter at 1.

Based on this accumulated experience, the letter states that, "for States that expand eligibility above an effective level of 250 percent of the FPL," CMS is "clarifying that the reasonable procedures adopted by states to prevent crowd-out . . . should include the above five general crowd-out strategies." *Id.* at 1. The letter further states that CMS "will expect" such a state to incorporate three important components as part of these strategies:

- The level of cost-sharing imposed on SCHIP beneficiaries above 250% FPL should not be more favorable than the cost-sharing imposed by competing private plans by more than one percent of family income[4];

- A minimum of a one-year uninsurance period should be required before individuals with family incomes above 250% FPL may switch to SCHIP from private coverage; and

- Monitoring and verification should include information regarding the availability of coverage through noncustodial parents.

SHO Letter at 2.

The letter further explains that, in order not only to prevent crowd-out but also to ensure that the state's SCHIP program operates "in an effective and efficient manner that is coordinated with other sources of health benefits coverage," 42 U.S.C. § 1397aa(a), CMS "will ask for . . . the following assurances" before a state extends coverage above 250% FPL:

- Assurance that the state has enrolled at least 95 percent of children below the 200% FPL level who are uninsured and eligible for either SCHIP or Medicaid;

- Assurance that the number of children in this target population (*i.e.*, below 200% FPL) who are insured through private employers has not decreased by more than two percentage points over the past five years; and

- Assurance that the state is current with all reporting requirements, including those relating to crowd-out.

Id.

[4] The letter creates an exception where cost-sharing is set at five percent of family income, *see id.*, which is the maximum level of cost-sharing allowed by regulation, *see* 42 C.F.R. § 457.560.

CMS described this policy guidance as a "review strategy," and stated that it "will work with States that currently provide services to children with effective family incomes over 250 percent of the FPL" to amend their plans. *Id.* CMS further stated that it "would not expect any effect on current enrollees from this review strategy," and that it anticipates that "the entire program will be strengthened by the focus on effective and efficient operation of the program for the core uninsured targeted low-income population." *Id*. Finally, the letter states that CMS "expect[s] affected States to amend their SCHIP state plan . . . in accordance with this review strategy within 12 months, or CMS may pursue corrective action." *Id*.

4. Administrative and Judicial Review Procedures

As its terms make clear, the SHO Letter presages the policy CMS intends to follow in applying existing program requirements in future administrative proceedings. Those proceedings may take two forms, depending on whether they are initiated by the state or the agency. However, both proceedings provide the state with the opportunity for a full hearing before the policies announced in the SHO Letter may be finally applied in any review by CMS of the state's plan material. Moreover, both provide the opportunity for subsequent judicial review.

a. Plan Amendment Proceedings. As stated at the end of the SHO Letter, CMS expects "affected states" (*i.e.*, states whose currently approved plans extend coverage beyond 250% FPL) to amend their plans within 12 months to conform to the letter's guidance. The SCHIP regulations provide that a state may amend its plan at any time, 42 C.F.R. § 457.60, and that it must do so whenever necessary to reflect "[c]hanges in [*inter alia*] . . . policy interpretations . . . that affect provisions in the approved State plan," *id.* § 457.60(a).

Once a state submits a plan amendment to CMS, it is deemed approved unless CMS notifies the state within 90 days that it is disapproved or that additional information is needed. 42 U.S.C. § 1397ff(c); 42 C.F.R. § 457.160(b). In the event that the amendment is disapproved, the

state may request reconsideration within 60 days. 42 U.S.C. § 1316(a)(2); 42 C.F.R. § 457.203(a). On reconsideration, the state is entitled to challenge the agency's decision in a full hearing on the record (which includes the opportunity for discovery). 42 C.F.R. § 457.203(b)-(c); *see also* 42 C.F.R. pt. 430, subpt. D. If the CMS Administrator at the end of the hearing process (or a court of appeals through subsequent judicial review) determines that CMS's initial disapproval of the amendment was incorrect, CMS will make the state whole by paying the incorrectly denied funds (*i.e.*, the funds the state would have received based on its proposed plan amendment from the time of the initial disapproval) in a lump sum. 42 C.F.R. § 457.203(d).

b. *Non-Compliance Proceedings.* In the event that a state affected by the SHO Letter does not submit a plan amendment within 12 months as requested, CMS has the authority to initiate non-compliance proceedings. Under the SCHIP regulations, the CMS Administrator may determine at any time that a previously approved state plan no longer meets approval requirements, *id*. § 457.150(c) – due to, *e.g.*, the state's failure to change its plan to conform to a new policy interpretation, *id*. §§ 457.204, 457.60(a). Before CMS may withhold program funds, however, the state is entitled to an opportunity for a hearing. 42 U.S.C. §§ 1397ff(c),(d); 42 C.F.R. §§ 457.203, 457.204. As the regulations state, CMS generally does not hold a hearing until attempting to resolve the issue through informal negotiations. 42 C.F.R. § 457.204(a)(2).

If a hearing nonetheless becomes necessary, then, as with plan amendment proceedings, the state is afforded a full hearing on the record. *Id.* § 457.206. If, at the end of the hearing, the Administrator finds that the state plan is in substantial non-compliance with statutory and regulatory requirements, CMS may withhold future payments, in whole or in part. *Id*. § 457.204(d). Such sanction is prospective only. *See N.J. v. HHS*, 670 F.2d 1262, 1271 (3d Cir. 1981).

c. *Judicial Review.* Any state dissatisfied with "the Administrator's final determination on approvability of plan material (§ 457.203) or compliance with Federal requirements (§ 457.204) has a right to judicial review." 42 C.F.R. § 457.208; *see also* 42 U.S.C. § 1397gg(e)(2)(B); 42 U.S.C. §§ 1316(a)-(b). The SCHIP statute expressly incorporates the administrative and judicial review provisions applicable to Medicaid programs, *see* 42 U.S.C. § 1397gg(e)(2)(B) (cross-referencing 42 U.S.C. § 1316), which allow a state to take appeal from a final plan-conformity determination by the agency in "the United States court of appeals for the circuit in which such state is located," 42 U.S.C. § 1316(a)(3). If such appeal is taken, the agency must file in the appellate court the record of the proceedings on which its determination was based. *Id.*; 42 C.F.R. § 457.208(b)(2). The court is bound by the agency's findings of fact if they are supported by substantial evidence in the record, but the court may, for good cause shown, remand the case to the agency to take further evidence. 42 U.S.C. § 1316(a)(4); 42 C.F.R. § 457.208(c). On remand, the Administrator may make new findings of fact and may modify his previous determination. 42 U.S.C. § 1316(a)(4); 42 C.F.R. § 457.208(d).

B. Plaintiffs' Complaint

On October 4, 2007, plaintiffs – the States of New York, Illinois, Maryland, and Washington – filed the instant complaint, which seeks to enjoin CMS "from disapproving any state child health plan or state plan amendment using the criteria stated in CMS's August 17, 2007 letter." Compl. at 22 (prayer for relief). Rather than relying on the review provisions of the SCHIP statute, plaintiffs bring suit under the APA. *Id.* Essentially, they mount two challenges to the SHO Letter. Substantively, they challenge the letter as imposing requirements that are arbitrary and capricious and in excess of statutory and regulatory authority; at bottom, they allege that the policies in the letter are impracticable and unnecessary to prevent crowd-out or to ensure

the program operates efficiently. *Id.* ¶¶ 3, 38-54. Procedurally, plaintiffs challenge the letter as an "illegal rulemaking not in conformance with applicable requirements of the [APA]." *Id.* ¶ 3.

The states are not identically situated. Notably, only Maryland has a currently approved plan that extends coverage beyond 250% FPL (specifically, to 300% FPL). *Id*. ¶¶ 25-27. Yet its SCHIP program is an expansion of its Medicaid program, as opposed to a separate SCHIP program, *id.* ¶ 25, and CMS has not yet addressed whether or how the SHO Letter applies to Medicaid-based SCHIP programs. *See infra* at 23. The remaining three plaintiffs merely are seeking, or contemplating seeking, to amend their plans to extend coverage above 250% FPL in the future. Thus, New York's currently approved plan covers children with effective family incomes up to 250% FPL, but the state is currently seeking to amend its plan in order to extend coverage up to 400% FPL. Compl. ¶¶ 20-24. Washington's currently approved plan provides coverage up to 250% FPL, but the state claims it intends at some unspecified date in the future to seek approval for a plan amendment extending coverage up to 300% FPL. *Id.* ¶¶ 28-32. Illinois' currently approved plan authorizes coverage up to 200% FPL, but the state (which has exhausted its federal SCHIP allotment) alleges it may eventually seek to amend its plan to provide coverage at some unspecified level above 200% FPL, if its federal allotment is increased. *Id.* ¶ 33-37.

CMS has not initiated compliance proceedings against any of the plaintiff states. Nor have any of the plaintiffs sought to work with CMS to develop a mutually acceptable plan amendment that conforms to the SHO Letter – except for New York, which proposed its plan amendment in April 2007, before the SHO Letter was issued. After extensive informal exchanges between CMS and the state, New York's proposed amendment was initially rejected on September 7, 2007 by the CMS Administrator, who found, consistent with the SHO Letter, that the amendment failed to include reasonable procedures to prevent substitution. *See* Declaration

of Serrin Turner ("Turner Decl."), Ex. A.[5] Several weeks after plaintiffs' complaint was filed, New York requested a full hearing on the record in order to contest the Administrator's decision rejecting the amendment. At that hearing, scheduled for later this year, New York intends to raise the very same challenges raised here. *See* Turner Decl., Ex. B, at 2 (letter from New York requesting reconsideration on the ground that the standards set forth in the SHO Letter "exceed the authority vested in the Secretary" and "constitute illegally promulgated regulations"). These administrative proceedings remain ongoing and are currently in discovery.

ARGUMENT

POINT I

THIS COURT LACKS JURISDICTION OVER THE COMPLAINT

A. The Case Is Not Ripe for Review

The Court should dismiss this action for lack of jurisdiction because it is not ripe. The ripeness doctrine serves "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Air Espana v. Brien*, 165 F.3d 148, 152 (2d Cir. 1999) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 148-49 (1967)). Ripeness turns on: "(1) whether an issue is fit for judicial decision and (2) whether and to what extent the parties will endure hardship if decision is withheld." *Simmonds v. INS*, 326 F.3d 351,

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[5] The Court may refer to material outside the pleadings in deciding a Rule 12(b)(1) motion. *See Robinson v. Gov't of Malaysia*, 269 F.3d 133, 141 n.6 (2d Cir. 2001). The material attached to the Turner Declaration is submitted only as background for defendant's jurisdictional motion. It is not proffered as evidence relevant to the merits of plaintiffs' APA challenge – which would be improper, because APA review is confined to the administrative record. *See infra* at 20-21.

359 (2d Cir. 2003). As explained below, plaintiffs' claims are not fit for judicial decision, and plaintiffs will not endure significant hardship if review is withheld at this juncture.

1. The Case Is Not Fit for Judicial Decision

The "fitness" determination "requires consideration of a variety of pragmatic factors: whether the agency's actions or inactions challenged in the law suit are 'final,' whether the issues presented for review are primarily legal as opposed to factual in nature, and whether administrative remedies have been exhausted at least to the extent that an adequate factual record has been established." *Seafarers Int'l Union of North America, AFL-CIO v. U.S. Coast Guard*, 736 F.2d 19, 26 (2d Cir. 1984). None of these factors are present here.

a. The SHO Letter Does Not Constitute Final Agency Action.

In bringing this suit, plaintiffs have eschewed the specific avenue of relief afforded by statute – improperly, as explained below, *see infra* Point I.B – and instead rely solely on the APA. But even by the APA's terms the case is unripe, for the APA explicitly requires as a jurisdictional prerequisite that agency action be final before review may be sought under the statute. *See Air Espana*, 165 F.3d at 152 (citing 5 U.S.C. § 704). Section 704 makes clear that "[a] preliminary, procedural, or intermediate agency action or ruling" is not directly reviewable under the APA but instead is subject to review only on "review of [a] final agency action." In order for an agency action to be "final," it must "mark the consummation of the agency's decisionmaking process" and be an action "by which rights or obligations have been determined or from which legal consequences will flow." *See Air Espana*, 165 F.3d at 152-53 (quoting *Top Choice Distribs., Inc. v. USPS*, 138 F.3d 463, 466 (2d Cir. 1998) (quoting *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997))).

The SHO Letter is merely a "preliminary" action, not a "final" one. It does not mark the consummation of any administrative proceeding; nor does it constitute a determination that a

particular state's plan or plan amendment fails to conform to federal requirements, from which concrete legal consequences (*e.g.*, suspension of the state's SCHIP funding) might flow. Rather, by its own terms, the letter merely indicates how CMS expects to assess plan conformity in *future* administrative proceedings. *See* SHO Letter at 2 ("[W]e *will expect* that, for states that expand eligibility above an effective level of 250 percent of the FPL, the specific crowd-out strategies identified in the State child health plan [will] include . . ."); *id.* ("we *will ask* for such a State to make the following assurances . . ."); *id.* ("we *expect* affected States to amend their SCHIP state plan . . . within 12 months, or CMS *may* pursue corrective action") (all emphases added).

In the parlance of the APA, the SHO Letter is merely a general statement of policy or interpretive rule that "announces the course which the agency intends to follow in future adjudications." *Pac. Gas & Elec. Co. v. FPC*, 506 F.2d 33, 38 (D.C. Cir. 1974). As such, the letter has no binding effect by itself, but only serves to guide future decision-making. *See Pub. Citizen, Inc. v. U.S. Nuclear Regulatory Comm'n*, 940 F.2d 679, 682 (D.C. Cir. 1991) ("The policy statement makes it clear that the decisions have not yet been taken . . . ."); *Pac. Gas*, 506 F.2d at 48 ("It is the policy which the Commission hopes to apply in future proceedings but there is no assurance that this specific policy will be imposed . . . ."). Accordingly, the effect of the letter will not be reflected in any final agency action until it is definitively applied to a specific state plan or plan amendment through the agency's adjudicative procedures. *Hudson v. FAA*, 192 F.3d 1031, 1035 (D.C. Cir. 1999) ("Typically the *substance* of a true policy statement [cannot] be contested . . . because it would be regarded as not ripe until it was reflected in subsequent agency actions . . . .") (emphasis in original).

Such adjudication would occur only through a plan amendment proceeding or compliance proceeding. *See* 42 C.F.R. §§ 457.203, 457.204. Yet no compliance proceeding has

been brought against any plaintiff. Nor have any of plaintiffs engaged the plan amendment process except for New York, and New York is still exhausting its remedies under that process.

Whether CMS will finally deny New York's amendment, or take any final adverse action against any of the other plaintiffs based on the SHO Letter, can only be determined through the completion of administrative proceedings. Unlike a regulation, the SHO Letter does not constitute binding law that the agency must follow: the state is free to challenge the policies outlined in the SHO Letter during the administrative process, and the agency is free to depart from them. *See Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1046 (D.C. Cir. 1987) (general statements of policy allow agencies to announce their "tentative intentions for the future without binding themselves"); *cf.* 42 C.F.R. § 457.150(c) (giving the CMS Administrator ultimate authority to determine whether state plan material meets federal requirements). Thus, it remains to be seen what ramifications the letter will have in practice.

The administrative process provides ample opportunity for informal negotiation, through which the parties can explore room for compromise. Indeed, the SHO Letter specifically states that CMS will work with affected states in revising their state plans in response to the letter, SHO Letter at 2, just as CMS has worked with states to formulate crowd-out strategies in the past, *see* 66 Fed. Reg. at 2,601. Further, if the parties cannot bridge their differences informally, then the state is entitled to press its case through a full hearing on the record. 42 U.S.C. § 1316(a)(2); 42 C.F.R. § 457.203; 42 C.F.R., pt. 430, subpt. D. Based on the state's submissions in that hearing, the CMS Administrator may find it appropriate to carve out exceptions to the policies contained in the SHO Letter, or he may decline to follow them at all.

For example, although plaintiffs complain that the 12-month uninsurance period called for in the SHO Letter would cause undue hardship because "[n]o exceptions . . . will be permit-

ted," *see* Compl. ¶ 48, in fact the SHO Letter is silent on the subject of exceptions. In the past, CMS has encouraged states to include reasonable exceptions as part of such uninsurance periods (*e.g.*, exceptions for loss of private insurance through no fault of the family, death of a parent, *etc.*), *see* 66 Fed. Reg. at 2,603-04, and nothing in the SHO Letter indicates that CMS will not permit similar exceptions going forward. Only actual application of the letter in a final agency determination will provide a definitive answer.

As another example, while plaintiffs complain that it is simply impossible for them to insure 95 percent of the core SCHIP target population – one of the assurances asked for in the SHO Letter as a precondition to extending coverage beyond 250% FPL – it is unclear how CMS intends to calculate whether the state has met this threshold. In negotiating a mathematical model with the state, CMS could take into account some of the practical difficulties involved in maximizing enrollment – *e.g.*, by excluding children not physically residing in the state from the target population. As another form of compromise, CMS could require the state to implement a gradual plan to meet the 95-percent threshold over the long term if there are special reasons why the state cannot meet the threshold under current circumstances. Again, the SHO Letter is mere policy guidance and not binding law, so the agency is free to apply it flexibly.

In short, this is not a case in which "no further administrative proceedings are contemplated." *Cf. Abbott Labs.*, 387 U.S. at 149. Rather, "[w]ere [the Court] now to decide the issues [plaintiffs] present [it] might inadvertently foreclose or undermine a decision properly made by the [agency]." *In re Drexel Burnham Lambert Group Inc.*, 995 F.2d 1138, 1146 (2d Cir. 1993) (holding case unripe given that agency "retain[ed] substantial discretion" as to final decision to be made in the future); *Isaacs v. Bowen*, 865 F.2d 468, 478 (2d Cir. 1989) (holding Medicare challenge unripe where it concerned "proposals subject to change"). Such premature interven-

tion would deny CMS "an opportunity to correct its own mistakes and to apply its expertise" – contrary to the central purpose of the finality requirement. *Occidental Chem. Corp. v. FERC*, 869 F.2d 127, 129 (2d Cir. 1989) (quoting *FTC v. Standard Oil Co.*, 449 U.S. 232, 242 (1980)); *see also Seafarers Int'l Union*, 736 F.2d at 26 (agency action not final until "the process of administrative decision-making has reached a stage where judicial review will not be disruptive of the agency process"). Indeed, this risk is particularly acute given that plaintiff New York is currently pursuing the very same legal challenges presented here in ongoing administrative proceedings. *See Am. Savings Bank, FSB v. UBS Fin. Servs.*, 347 F.3d 436, 440 (2d Cir. 2003) ("The fact that [plaintiff] has not yet exhausted its administrative remedies counsels in favor of invoking the prudential ripeness doctrine. This approach would avoid both interference with ongoing administrative activity and prematurely addressing [] novel issues of first impression raised in this appeal . . . . Moreover, our review will only benefit by awaiting the [agency's] views on these issues involving its own regulations.").

b. Plaintiffs' Challenge to the SHO Letter Turns on Factual Issues that Require Further Administrative Development

Another reason the case is unripe is that it turns on factual questions that have yet to be explored at the administrative level. Plaintiffs' substantive challenge to the policies announced in the SHO Letter comprises various claims that these policies are "arbitrary and capricious" and "contrary to law" because they are impracticable or exceed what is necessary in order to prevent crowd-out and to provide insurance to low-income children in an efficient and effective manner. These claims cannot be resolved in a factual vacuum. *Cf. Toilet Goods Ass'n, Inc. v. Gardner*, 387 U.S. 158, 163-164 (1967) (rejecting as unripe challenge to a regulation based on statutory authority to promote "efficient enforcement," given that such a challenge "will depend not mere-

ly on an inquiry into statutory purpose," but on an understanding of "what types of enforcement problems are encountered" under the statute).

For example, plaintiffs claim that it would be impossible for them to enroll 95 percent of children below 200% FPL who are eligible for SCHIP or Medicaid. *See* Compl. ¶ 44 (contending that the "practical consequence" of this requirement is to "bar states" from extending SCHIP coverage above 250% FPL). However, this claim ultimately turns on issues of fact – concerning, for example, what steps the states have taken to enroll children below 200% FPL to date, why those steps have failed to achieve 95-percent enrollment, what further steps the states could take to boost enrollment of this core target population, and what costs and trade-offs such further steps would entail. These facts are not before this Court, as they have yet to be developed through an appropriate administrative proceeding.

Similarly, plaintiffs claim that a 12-month uninsurance period "does not constitute a reasonable procedure designed to prevent [crowd-out]," citing the fact that "only 2 states have a 12-month waiting period" while all others have uninsurance periods of six months or less. Compl. ¶ 50. This claim, too, turns on questions of fact – most notably, whether the shorter uninsurance periods imposed by most states have proven sufficiently effective at preventing crowd-out. The recent CBO study concluding that crowd-out remains a substantial problem for the SCHIP program would seem to answer that question in the negative; but proper factual development of the issue can only occur through the administrative process.

As a third example, plaintiffs claim that states will have "considerable difficulty" obtaining information about the levels of cost-sharing imposed by competing private plans, making it impracticable for states to impose comparable levels of cost-sharing on SCHIP beneficiaries above 250% FPL. Compl. ¶ 53. Yet it is hardly obvious that the states cannot obtain sufficient

information about competing private plans for this purpose, especially given that private insurance plans are comprehensively regulated by the states. Again, the issue is one of fact that depends on what sources of data are available to the states regarding private health plans and what information can be gleaned from those sources relevant to cost-sharing.

In short, there is no way for this Court to evaluate the reasonableness of the SHO Letter in the abstract, for plaintiffs' various challenges to it are inextricably bound up with questions of fact. Because it is undeniable that "further factual development would significantly advance [a reviewing court's] ability to deal with the legal issues presented," the case is unripe. *Nat'l Park Hospitality Ass'n v. Dep't of the Interior,* 538 U.S. 803, 812 (2003) (quoting *Duke Power Co. v. Carolina Envt'l Study Group, Inc*., 438 U.S. 59, 82 (1978)); *cf. Simmonds*, 326 F.3d at 359 ("[I]ssues have been deemed ripe when they would not benefit from any further factual development and when the court would be in no better position to adjudicate the issues in the future than it is now.").[6]

c. No Administrative Record Has Been Developed that Could Serve as the Basis for Judicial Review

Not only is judicial review at this stage improper for the reasons set forth above; it is impossible in the absence of any administrative record on which judicial review could be based. An appropriate administrative record can be compiled only through completion of the agency's adjudicative process. That process allows both the state and the agency to present evidence in

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[6] Indeed, even "a regulation is not ordinarily considered the type of agency action 'ripe' for judicial review until the scope of the controversy has been reduced to more manageable proportions, and its factual components fleshed out, by some concrete action applying the regulation to the claimant's situation in a fashion that harms or threatens to harm him." *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 891 (1990). There is even greater reason to await actual application of a general policy statement, given that the agency is not even bound to apply it in the first place.

support of their positions in a full trial-type hearing, ultimately yielding a reasoned final agency decision that is grounded in – and can be evaluated upon – a complete evidentiary record. *See* 42 U.S.C. § 1316(a)(3) (contemplating judicial review of plan-conformity decisions based on "the record of the proceedings on which [the HHS Secretary] based his determination"); 42 C.F.R. § 457.208(b)(2) (requiring CMS Administrator to file such record where his determination is appealed). In the absence of such a record, there is simply no basis on which the Court could resolve the factual issues bound up with plaintiffs' claims. *See Nutritional Health Alliance v. Shalala*, 144 F.3d 220, 226 (2d Cir. 1998) (finding dispute unripe given that it turned in part on claims that were "particularly difficult to resolve in the abstract and without a full record"); *Seafarers Int'l Union*, 736 F.2d at 27-28 (finding challenge unripe given that "there is simply no administrative record developed which the district court can review").

Although plaintiffs have contended that the relevant facts in this case "can be developed through either declarations for purposes of summary judgment or, failing that, at trial," Pfs.' Pre-Mot. Conf. Ltr. dated Jan. 15, 2008, at 3, this contention is misguided. It is black-letter law that, in an APA case, "the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court." *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743 (1985) (quoting *Camp v. Pitts*, 411 U.S. 138, 142 (1973)). The reviewing court in an APA case "sits as an appellate tribunal," not as a court "authorized to determine in a trial-type proceeding" the lawfulness of the agency's action. *Marshall Cty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1225 (D.C. Cir. 1993). Accordingly, in order for an APA case to be a ripe, "administrative remedies [must] have been exhausted at least to the extent that an adequate factual record has been established." *Seafarers Int'l Union*, 736 F.2d at 26. Because this requirement is plainly not met here, the case is not ripe.

2. Denial of Review at This Stage Will Not Impose a Hardship upon the Parties

Not only is the case unfit for judicial review, but withholding review will not impose cognizable hardship. In assessing hardship under the ripeness doctrine, the question is "whether the challenged action creates a direct and immediate dilemma for the parties." *Simmonds*, 326 F.3d at 360 (quoting *Marchi v. Bd. of Coop. Educ. Servs.*, 173 F.3d 469, 478 (2d Cir. 1999)). "The mere possibility of future injury, unless it is the cause of some present detriment, does not constitute hardship." *Simmonds,* 326 F.3d at 360. Here, the SHO Letter does not create a "direct and immediate dilemma" for the plaintiffs, as none of the plaintiffs are directly or immediately required to comply with its terms.

Three of the four plaintiffs – New York, Washington, and Illinois – do not extend coverage above 250% under their currently approved plans, and thus the SHO Letter does not require them to make any change in their plans as presently constituted. It is true that these states have stated that they want to expand coverage beyond the 250% FPL level in the future, and that New York is actively seeking such an expansion. But a change of this nature requires a plan amendment that must be approved by CMS in any event, regardless of the SHO Letter. (Indeed, plaintiff New York proposed its amendment to this effect before the SHO Letter was even issued.) Thus, there is no harm in requiring these plaintiffs to complete the plan amendment process before challenging the SHO Letter in court, because there can be no harm in requiring plaintiffs to do something they are required to do anyway. *Cf. Reno v. Catholic Social Servs., Inc.*, 509 U.S. 43, 58 (1993) (finding no hardship in delaying review of regulation limiting access to government benefit, given that plaintiffs were not entitled to the benefit "automatically" in the absence of the regulation but rather were independently required "to take further affirmative [administrative] steps, and to satisfy criteria beyond those addressed by the disputed regulations").

Plaintiffs would be no worse off at the end of the plan amendment process than they are now. If any state's proposed amendment is denied at the end of that process, the state's injury will ripen at that point and the state may then seek judicial review of that denial – including review of any aspect of the SHO Letter on which the denial is based. If the state ultimately prevails in obtaining approval for its amendment, whether after an agency hearing or through a court challenge, any federal reimbursement denied to the state in the interim would be restored. *See* 42 C.F.R. § 457.203(d).

As for plaintiff Maryland, while its currently approved plan does extend coverage above 250% FPL, its program is designed as an expansion of its Medicaid program rather than a separate program under SCHIP. CMS has not addressed whether it will apply the review strategy outlined in the SHO letter, or any similar review strategy, to Medicaid expansions. The SHO Letter is largely based on SCHIP crowd-out regulations, which, by their terms, apply only to separate SCHIP programs, not Medicaid-based programs. *See* 42 C.F.R. § 457.800(c) (stating that substitution regulations apply to "separate child health programs"). The SHO Letter does not purport to apply to Medicaid-based SCHIP programs, nor has the agency taken any definitive action to such effect.

In any event, even if CMS might eventually decide to apply the SHO Letter to Medicaid-based programs, it has certainly not yet done so through any compliance action brought against Maryland. The SHO Letter itself merely gives notice that CMS *may* initiate such compliance actions *in the future* if a state fails to amend its plan as the letter requests. As the letter makes clear, no such action will be brought against any state affected by the letter until August 2008, at the earliest. *See Nat'l Park Hospitality Ass'n*, 538 U.S. at 810 (finding challenge to regulation unripe where the regulation merely "announce[d] the position [the agency] will take" in future

contract disputes); *cf. Schulz v. IRS*, 395 F.3d 463, 464 (2d Cir. 2005) (rejecting challenge to IRS summons as unripe because such summonses "have no force or effect unless the Service seeks to enforce them through [an enforcement] proceeding").

Moreover, even the initiation of a compliance proceeding would not place Maryland in any direct and immediate dilemma. *See FTC v. Standard Oil*, 449 U.S. at 241-42 (rejecting as unripe challenge to agency's filing of administrative complaint, given that a complaint does not represent a "definitive agency position" but rather is "a determination only that adjudicatory proceedings will commence"); *Top Choice Distributors*, 138 F.3d at 467 ("[T]he administrative complaint has no effect except to force plaintiffs to respond . . . . Review of the [agency's] action is therefore premature."). Rather, only at the *conclusion* of the proceeding, if non-compliance were found, would Maryland face a direct and immediate choice between limiting its coverage in line with the SHO Letter and giving up program funds. By then, however, Maryland would have aired its arguments in the administrative process and could seek immediate judicial review. *Cf. Toilet Goods*, 387 U.S. at 165 (finding minimal hardship in denying pre-enforcement review, because party's non-compliance would "at most lead only to a suspension of certification . . . , a determination that can then be promptly challenged through an administrative procedure, which in turn is reviewable by a court"); *Seafarers Int'l Union*, 736 F.2d at 28 ("[I]n weighing the hardship to the parties of withholding court consideration, the fact that there are available administrative remedies which are not . . . shown to have been exhausted . . . is . . . crucial.").

Further, it is important to note that at no point – not even at the end of compliance proceedings – would Maryland be required to drop current beneficiaries from its rolls in order to come into compliance. The SHO Letter expressly states that CMS does not expect the policies in the letter to have "any effect on current enrollees." SHO Letter at 2. In other words, all current

enrollees in families with effective income levels above 250% FPL will be grandfathered into the program even if the state ends up having to cap eligibility for future enrollees at 250% FPL. Thus, Maryland faces categorically no threat – direct, immediate, or otherwise – of having to shrink its current enrollment as a result of the SHO Letter.

In sum, none of the plaintiffs stand to suffer any immediate hardship in response to the SHO Letter. Their current enrollees will remain unaffected by the letter according to its own terms. Nor must any of the states immediately refrain from adding enrollees to its program with family incomes above 250% FPL on pain of losing federal funding. New York, Washington, and Illinois are not presently entitled to such funding in the first place, because their currently approved plans do not extend coverage above 250% FPL. And Maryland will not face this choice unless and until CMS decides to apply the SHO Letter to Medicaid-based programs and compliance proceedings against Maryland are initiated and consummated. *See Clearing House Ass'n v. Cuomo*, 510 F.3d 105, 124 (2d Cir. 2007) (finding case unripe where "compliance with [the] challenged law, prior to its enforcement, would [not] force [plaintiffs] to incur immediate expenses, make changes in their daily activity, or otherwise . . . affect their 'primary conduct'"); *Roosevelt Campobello Int'l Park Comm'n v. EPA*, 684 F.2d 1034, 1040 (1st Cir. 1982) (holding that agency action is not ripe for review "if it makes no change in the *status quo* itself, but rather requires further administrative action other than the possible imposition of sanctions, before rights, obligations or duties arise") (internal quotations omitted).

Hence, the only detriment the states face now is the delay and uncertainty associated with exhausting their administrative remedies. The law is clear, however, that such inconveniences are not enough to constitute "hardship" for ripeness purposes. *Nat'l Park Hospitality Ass'n,* 538 U.S at 811 (rejecting argument "that mere uncertainty as to the validity of a legal rule constitutes

a hardship for purposes of the ripeness analysis"); *Occidental Chem.*, 869 F.2d at 129 ("[A]gency delay is not a factor in determining ripeness."); *see also M. G. Davis & Co. v. Cohen*, 369 F.2d 360, 363 (2d Cir. 1966) (holding that "[t]he usual factors of litigation expense and frustration due to delay, present in many administrative proceedings, are not such threatened injuries as will satisfy [a party's] obligation to exhaust administrative remedies" but instead are "'part of the social burden of living under government'") (quoting *Petroleum Exploration, Inc. v. Pub. Serv. Comm'n*, 304 U.S. 209, 222 (1938)).

As the Supreme Court has held even in the context of challenging a regulation: given that "only minimal, if any, adverse consequences" are entailed in pursuing such a challenge through an established administrative process, it is "wiser to require [plaintiffs] to exhaust this administrative process through which the factual basis of the [agency action] will certainly be aired and where more light may be thrown on the Commissioner's statutory authority and practical justifications for the regulation." *Toilet Goods*, 387 U.S. at 166. "Judicial review will then be available, and a court at that juncture will be in a better position to deal with the question of statutory authority." *Id.* The same is true here – even more so given that a policy statement rather than a regulation is at issue, so that there is no final agency action fit for review. *See DRG Funding Corp. v. Sec'y of HUD*, 76 F.3d 1212, 1215 (D.C. Cir. 1996) (stating that "claims of hardship will rarely overcome the finality and fitness problems inherent in attempts to review tentative decisions") (internal quotation marks omitted).

B. The Statutory Review Scheme Precludes Plaintiffs from Seeking Pre-Enforcement Review

Beyond ripeness, there is another reason why this Court lacks jurisdiction: the judicial review mechanism prescribed by the SCHIP statute provides the exclusive vehicle through which plaintiffs' claims may be litigated. Because that provision grants a right to judicial review only

where CMS has made a final determination that a state's plan or plan amendment does not meet federal requirements, and permits appeal only in federal appeals court, the provision precludes any action for pre-enforcement review in district court, as plaintiffs seek here.

As discussed, the SCHIP statute incorporates by reference the administrative and judicial review scheme applicable to the Medicaid program. *See* 42 U.S.C. §§ 1397gg(e)(2)(B) (cross referencing 42 U.S.C. § 1316). Under that scheme, a state is entitled to judicial review in federal appeals court with respect to any final determination by CMS disapproving a state's proposed plan or plan amendment or finding that the state's currently approved plan no longer conforms to federal requirements. *See* 42 U.S.C. § 1316(a)(3); *see also* 42 C.F.R. § 245.208(a) ("Any State dissatisfied with the Administrator's final determination on approvability of plan material (§ 457.203) or compliance with Federal requirements (§ 457.204) has a right to judicial review."); *N.J. v. HHS*, 670 F.2d at 1269-71 (explaining that "[s]ection 1316(a) explicitly provides for direct court of appeals review of all plan-nonconformity determinations").

Were this case ripe – that is, were it brought by a state seeking to challenge a final determination by the CMS Administrator – it would squarely fall within the exclusive scope of this provision. The central issue in the case is whether CMS has the authority to find a state plan or plan amendment in non-conformance with federal requirements based on the policy guidance contained in the SHO Letter. Such a finding is precisely the type of determination that § 1316(a) requires to be reviewed in the court of appeals. Although § 1316(a) does not specify that this appellate court jurisdiction is exclusive, the law is clear that if Congress specifically designates a forum for judicial review of certain administrative action, that forum is presumed exclusive for that category of action. *See Aquavella v. Richardson*, 437 F.2d 397, 402 (2d Cir. 1971) ("Where

the Medicare Act establishes procedures for review of the Secretary's decision, a court may not review that decision by any other means.").[7]

Plaintiffs cannot circumvent § 1316(a)'s exclusive *post*-enforcement review mechanism by bringing an action for *pre*-enforcement review in this Court. Congress was careful to specify in § 1316(a) when and where judicial review of plan-conformity disputes may take place: after the agency has made its final determination, review may be sought in federal appeals court. Plaintiffs are not free to seek review on any other terms.

The Supreme Court's decision in *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200 (1994), is directly on point. Plaintiff in that case, a mine operator, sought to challenge a regulation adopted by the Mine Safety and Health Administration. Like the plaintiffs here, the company chose not to seek review through the process provided by the relevant substantive statute (the Mine Act), which allowed for direct appellate review in the wake of a final agency decision. Instead, the company filed a pre-enforcement challenge in district court seeking to enjoin the agency from enforcing the regulation against it. *Id.* at 205-207. The Supreme Court held that the district court lacked subject matter jurisdiction to entertain plaintiff's challenge, even though "the [Mine] Act is facially silent with respect to pre-enforcement claims." *Id.* at 209. As the Court explained:

[7] *See also NRDC v. Abraham*, 355 F.3d 179, 193 (2d Cir. 2004) (holding that, in the face of a specific statutory grant of jurisdiction to the court of appeals, ambiguities should be resolved in favor of exclusive appeals court review); *CETA Workers' Organizing Comm. v. City of N.Y.*, 617 F.2d 926, 935 -936 (2d Cir. 1980) (holding statutory judicial review procedures to be exclusive where they "seem expressly designed to deal with complaints such as those made by appellants, and . . . any other interpretation would permit unnecessary duplication and conflicting litigation"); *Sun Enterprises v. Train*, 532 F.2d 280, 287 (2d Cir. 1976) (holding that statutory right of review in court of appeals "is, absent extraordinary conditions, exclusive")

> Petitioner's claims are "pre-enforcement" only because the company sued before a citation was issued, and its claims turn on a question of statutory interpretation that can be meaningfully reviewed under the Mine Act. Had petitioner persisted in its refusal to [comply with the regulation at issue], the Secretary would have been required to issue a citation and commence enforcement proceedings. Nothing in the language and structure of the Act or its legislative history suggests that Congress intended to allow mine operators to evade the statutory-review process by enjoining the Secretary from commencing enforcement proceedings, as petitioner sought to do here. To uphold the District Court's jurisdiction in these circumstances would be inimical to the structure and the purposes of the Mine Act.

Id. at 216.

The same concerns apply to this case. Like the Mine Act, the SCHIP statute contains a comprehensive administrative and judicial review scheme. *Compare* 42 U.S.C. § 1316 (establishing right to administrative hearing and subsequent judicial review in court of appeals) *with Thunder Basin*, 510 U.S. at 207-08 (explaining similar rights granted by Mine Act). Plaintiffs' claims can be meaningfully reviewed within the confines of this statutory scheme – including both plaintiffs' substantive claim that the guidance in the SHO Letter is contrary to the program statute and regulations, and their procedural claim that the guidance should have been issued through notice-and-comment rulemaking. As mentioned earlier, New York is currently pursuing these very claims before the agency. *See* Turner Decl., Ex. B, at 2. And these same claims may be pursued in appeals court under § 1316(a)(3) in the event of an adverse final agency decision. *See N.J. v. HHS*, 670 F.2d at 1276 (reviewing under § 1316(a) whether a new administrative requirement set forth in a "program instruction" interpreting an existing regulation was consistent with the Medicaid statute); *see also W. Va. v. Thompson*, 475 F.3d 204, 210 (4th Cir. 2007) (reviewing under § 1316(a) state's argument that criteria for CMS's denial of state's Medicaid plan should have been issued through notice-and-comment rulemaking).

Further, as in *Thunder Basin*, nothing in the relevant statutory provisions or their legislative history indicates that Congress intended to let states bypass § 1316(a) by seeking review of

CMS's requirements prior to their enforcement. To the contrary, by all appearances, Congress's intention was to render pre-enforcement review unnecessary by providing efficient mechanisms for enforcement. Thus, the statute requires the Secretary to act expeditiously in reviewing proposed plans and plan amendments. *See, e.g.*, 42 U.S.C. § 1397ff(c) (state SCHIP plan or plan amendment must be reviewed promptly and is considered approved unless CMS notifies the state within 90 days of its disapproval); 42 U.S.C. § 1316(a)(2) (if amendment is denied and state seeks reconsideration, CMS must promptly schedule hearing and issue a final determination within 60 days of the hearing's conclusion). The legislative history of § 1316 confirms that its provisions were "designed to assure that the States will not encounter undue delays in obtaining Federal determinations on acceptability of proposed State plan material." S. Rep. No. 89-404, *reprinted in* 1965 U.S.C.C.A.N. 1943, 2090-91 (legislative history of original Medicaid provisions). Notably, Congress also was aware of the importance of allowing the agency to attempt to resolve disputes at the administrative level through informal negotiations. Section 1316's legislative history notes that its administrative and judicial review provisions "are not intended to affect adversely the usual negotiation process between [HHS] and the States which, in nearly all instances, results in the development of a State plan or plan amendment that can be approved by the Secretary." *Id.* at 2090.

As in *Thunder Basin*, then, allowing plaintiffs to obtain pre-enforcement review of CMS's requirements in district court would undermine the review scheme specifically established by Congress and hamper CMS's administration of the program. *See*, *e.g.*, *Doe v. FAA*, 432 F.3d 1259, 1263 (11th Cir. 2005) ("The [complainants] simply cannot avoid the statutorily established administrative-review process by rushing to the federal courthouse for an injunction preventing the very action that would set the administrative-review process in motion."); *Great*

Plains Coop v. Commodity Futures Trading Comm'n, 205 F.3d 353, 355 (8th Cir. 2000) ("[Plaintiffs'] complaint is an impermissible attempt to make an 'end run' around the statutory scheme . . . . It would create two avenues of judicial review and would allow the plaintiff to short-circuit the administrative review process and the development of a detailed factual record by the agency."). Accordingly, as in *Thunder Basin*, the statute's specific review provisions should be construed to preclude such a result, and to require instead that the plaintiffs complete the administrative process before seeking review in federal appeals court.[8]

C. The Statutory Review Scheme Provides an Adequate Alternative to, and So Precludes, APA Review

Even if the SCHIP statute's judicial review mechanism were not preclusive, it would still effectively bar suit under the APA, which is plaintiffs' only route to establishing jurisdiction. It is axiomatic that jurisdiction may not be exercised over the federal government absent a waiver of sovereign immunity, *e.g.*, *FDIC v. Meyer*, 510 U.S. 471, 475 (1994), and the only waiver of sovereign immunity identified in plaintiffs' complaint is the APA, *see* Compl. ¶ 4.[9] APA review of final agency action is available, however, only if "there is no other adequate remedy in a

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[8] Such a construction would overlap with the ripeness requirement, which Congress presumptively intended. *See Reno v. Catholic Social Servs., Inc.*, 509 U.S. 43, 60 (1993) ("The ripeness doctrine and the Reform Act's jurisdictional provisions would thus dovetail neatly, and not necessarily by mere coincidence. Congress may well have assumed that, in the ordinary case, the courts would not hear a challenge to regulations specifying limits to eligibility before those regulations were actually applied to an individual, whose challenge to the denial of an individual application would proceed within the Reform Act's limited scheme.").

[9] Plaintiffs' jurisdictional statement also cites the federal question jurisdiction statute, 28 U.S.C. § 1331, and the "Little" Tucker Act, 28 U.S.C. § 1346(a)(2). Compl. ¶ 4. But the federal question jurisdiction statute "is in no way a general waiver of sovereign immunity." *Doe v. Civiletti*, 635 F.2d 88, 94 (2d Cir. 1980). And the Little Tucker Act is inapplicable because it waives immunity only for small contract claims, which are not presented here.

court." 5 U.S.C. § 704. Review under the APA is thus unavailable here because the SCHIP statute's judicial review provision affords such an adequate alternative.

Any state that exhausts its administrative remedies and receives an adverse final agency decision – whether in the form of a denial of plan amendment or a finding of non-compliance – may take appeal under 42 U.S.C. § 1316(a)(3). And in that appeal, as discussed above, the state can raise the same substantive and procedural challenges raised here. Moreover, a court of appeals would apply essentially the same standard of review in that appeal as would apply in an APA action. *See* 42 U.S.C. § 1316(a)(4) (requiring appeals court to accept the agency's findings of fact if supported by "substantial evidence"); *see also Mem'l Hosp./Adair County Health Ctr. v. Bowen*, 829 F.2d 111,117 (D.C. Cir. 1987) (explaining that "substantial evidence" test entails same level of scrutiny as "arbitrary and capricious" test).

As the Supreme Court has held, the APA's "adequate remedy" provision makes "clear that Congress did not intend the general grant of review in the APA to duplicate existing procedures for review of agency action." *Bowen v. Mass.*, 487 U.S. 879, 903 (1988). Hence, it is well established that an opportunity for judicial review at the conclusion of a statutorily prescribed review process constitutes an "adequate remedy in a court" barring judicial review under the APA. *See, e.g., FCC v. ITT World Commc'ns, Inc.*, 466 U.S. 463, 468 (1984) (finding suit to enjoin agency action as *ultra vires* to be unreviewable under the APA where statute at issue provided for judicial review in the court of appeals); *CETA Workers' Organizing Comm.*, 617 F.2d at 935-36 (APA review precluded given availability of review under Comprehensive Employment and Training Act); *Sun Enterprises*, 532 F.2d at 288 (APA review precluded given availability of review under Water Act); *see also Niagara Mohawk Power Corp. v. FERC*, 306 F.3d 1264, 1268 (2d Cir. 2002) (APA review precluded given that plaintiff "may obtain complete re-

lief with respect to all of the contracts at issue" in lawsuit against state public service agency); *N.Y. City Employees' Retirement Sys. v. S.E.C.*, 45 F.3d 7, 14 (2d Cir. 1995) (APA review precluded given that plaintiffs had alternative remedies to suing SEC); *cf. Japan Whaling Ass'n v. Am. Cetacean Soc'y*, 478 U.S. 221, 230 n.4 (1986) (finding APA review proper because the issue of whether the agency's action was lawful "will not otherwise arise in litigation"). Accordingly, the SCHIP statute's judicial review scheme precludes APA review here.

POINT II

THE SHO LETTER WAS NOT REQUIRED TO BE ISSUED THROUGH NOTICE-AND-COMMENT RULEMAKING

For the reasons discussed above, even plaintiffs' procedural challenge to the SHO Letter is unripe, and in any event can be raised only in an appeal brought under the statutorily prescribed review scheme. Thus, the Court need not and should not reach it. However, if this Court were nonetheless to find that it has jurisdiction to review any aspect of plaintiffs' case, the only potentially purely legal claim that the Court could resolve in the absence of an administrative record is plaintiffs' procedural claim that the policies outlined in the SHO Letter were required to be promulgated through notice-and-comment rulemaking. Should the Court reach this claim, it should reject it under Rule 12(b)(6). The SHO Letter is merely a general statement of policy or interpretive rule, not a legislative rule, and as such it is specifically exempted from the APA's notice-and-comment requirements. *See* 5 U.S.C. § 553(b)(3)(A) (notice-and-comment requirements do not apply to "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice").

As the D.C. Circuit explained in *Pacific Gas*, *supra*, the seminal case on general statements of policy:

> An administrative agency has available two methods for formulating policy that will have the force of law. An agency may establish binding policy through

> rulemaking procedures by which it promulgates substantive rules, or through adjudications which constitute binding precedents. A general statement of policy is the outcome of neither a rulemaking nor an adjudication; it is neither a rule nor a precedent but is merely an announcement to the public of the policy which the agency hopes to implement in future rulemakings or adjudications. A general statement of policy, like a press release, presages an upcoming rulemaking or announces the course which the agency intends to follow in future adjudications.

506 F.2d at 38 (footnotes omitted). By disseminating policies to the public before their actual application, general statements of policy serve several beneficial functions: they promote transparency, facilitate long-range planning within the regulated field, and promote uniformity in agency decision-making. *Id.*

The "critical distinction" between a legislative rule and a general statement of policy is that the former "has the force of law" whereas the latter does not. *Id.* Thus, in administrative proceedings, a legislative rule (*e.g.*, a regulation) is generally not subject to challenge by the parties: it is binding law, and the agency needs no justification for applying the rule besides the existence of the regulation itself. *Id.* By contrast, because a general statement of policy only announces the agency's future plans, "[t]he agency cannot apply or rely upon a general statement of policy *as law*." *Id.* (emphasis added). Rather, when the agency ultimately applies the policy in a particular situation, it must be prepared to support the policy based on the agency's authority under relevant statutory and regulatory provisions, "just as if the policy statement had never been issued." *Id.*

Courts have similarly distinguished legislative rules from interpretive rules. Like general statements of policy, interpretive rules can announce an agency's "intended course of action" or "its tentative view of the meaning of a particular statutory term." *White v. Shalala*, 7 F.3d 296, 303 (2d Cir. 1993) (internal quotation marks omitted). Further, like general statements of policy, interpretive rules have no binding force of their own but are wholly derivative from existing law. As the Second Circuit has explained, legislative rules "create new law, rights, or duties in what

amounts to a legislative act," while interpretive rules merely "clarify an existing statute or regulation." *White*, 7 F.3d at 303; *cf. N.Y. City Employees' Retirement Sys.*, 45 F.3d at 13 (a rule is a legislative rule if "'in the absence of the rule, no legislative basis would exist for an enforcement action'") (quoting *Am. Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993)).[10]

The SHO Letter qualifies as a general statement of policy or interpretive rule under the foregoing criteria. The letter has no binding force itself. Rather than being a legislative rule, it affords states the benefit of advance notice of the approach the agency intends to follow in *future* adjudications of state plans – which is where binding decisions will be made. *See* SHO Letter at 2 ("we *will expect* . . . the specific crowd-out prevention strategies identified in the State child health plan to include . . ."); *id*. ("we *will ask for* such a State to make the following assurances . . ."); *id*. ("we *expect* affected States to amend their SCHIP state plan . . .") (all emphases added). Moreover, the letter makes clear that the policies it announces have no force of law independent of existing statutory and regulatory requirements. By its own terms, the letter merely "clarifies" how CMS will apply "existing statutory and regulatory requirements" going forward. *See* SHO Letter at 1 (citing relevant statutory and regulatory provisions). Thus, to the extent that CMS rejects state plan material based on the SHO Letter in any future administrative proceeding, it will need to defend that decision as consistent with those existing requirements.

[10] The difference between interpretive rules and general statements of policy would seem to be a matter of degree. Typically, "interpretive rules" are used to describe agency interpretations of particular statutory or regulatory language, whereas general statements of policy describe more broadly "the manner in which the agency proposes to exercise a discretionary power," *see Pac. Gas*, 506 F.2d at 38 n.17 (quoting the Attorney General's Manual on the APA 30 n.3 (1947)). However, the divide between the two concepts is not a sharp one, *see* Wright & Koch, 32 *Fed. Prac. & Proc.* § 8154 (2007) (stating that interpretive rules "need not interpret anything more concrete than the nebula of policy and law which make a total administrative scheme").

It is of course true that the SHO Letter may have the practical consequence of inducing states to comply with its guidelines in order to avoid any compliance action. "But this does not demonstrate that the guidelines have had *legal consequences*" of the sort that mark a legislative rule. *Ctr. for Auto Safety v. NHTSA*, 452 F.3d 798, 811 (D.C. Cir. 2006) (emphasis in original). Indeed, general statements of policy and interpretive rules inevitably tend to induce changes in the behavior of regulated parties, because their very function is to notify the public of how the agency intends to enforce statutory and regulatory standards in the future. Were that enough to trigger the APA's notice-and-comment requirements, then virtually all policy statements and interpretive rules would be subject to those requirements. *See, e.g., Am. Med. Ass'n v. Heckler*, 606 F. Supp. 1422, 1440 (C.D. Ind. 1985) ("The Secretary's statements in the 'Dear Doctor' letter are binding on the physicians only to the extent that they are on notice of how she intends to interpret [relevant statutory requirements] for enforcement purposes. All interpretative rules would be binding in that sense, as the regulated parties know that actions not in conformity with an agency's interpretation of a statute may be viewed by the agency as a violation of the statute. This does not, however, convert an interpretative rule into a legislative rule which has the 'force and effect of law.'").

Nor do plaintiffs have any basis for asserting that the SHO Letter constitutes a legislative rule merely because it represents a change from past practice. *Cf.* Compl. ¶ 38 ("CMS's new 'review strategy' effects substantive changes in the operation of the SCHIP program, but was not preceded by and is not supported by any change in the SCHIP statute or implementing regulations."). A general statement of policy can announce a *change* in policy and an interpretive rule can announce a *change* in interpretation: indeed, that is often the function of such pronouncements. As the Second Circuit has squarely held: "[A]n interpretive rule changing an agency's

interpretation of a statute is not magically transformed into a legislative rule." *White*, 7 F.3d at 304; *accord Metro. Sch. Dist. of Wayne Tp., Marion County, Ind. v. Davila*, 969 F.2d 485, 490 (7th Cir. 1992) ("[A] new position does not necessarily make a rule legislative rather than interpretive.") (citing *Mich. v. Thomas*, 805 F.2d 176, 182-84 (6th Cir. 1986); *Alcaraz v. Block*, 746 F.2d 593, 613-14 (9th Cir. 1984); *Am. Postal Workers Union v. USPS*, 707 F.2d 548, 559-60 (D.C. Cir. 1983)).

It is true that an agency may not announce a change of position in a general statement of policy or interpretive rule that is contrary *to existing regulations*; for a legislative rule can only be amended through a superseding legislative rule. *See Sweet v. Sheahan*, 235 F.3d 80, 91 (2d Cir. 2000) (a rule is considered legislative if it "'effectively amends a prior legislative rule'") (quoting *Am. Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1110-12 (D.C. Cir. 1993)). However, the SHO Letter does not announce any departure from the agency's existing regulations. Again, it merely explains how the agency intends to apply existing regulations – in particular, 42 C.F.R. § 457.805, which provides that a state plan must "include a description of reasonable procedures" to prevent crowd-out. In enforcing this regulation, the agency necessarily must adopt some view of what crowd-out procedures it will deem "reasonable," as the regulation itself leaves the question open. The SHO Letter simply explains the agency's current view on this subject. *See Ctr. for Auto Safety*, 452 F.3d at 808 (a policy statement is not transformed into a binding rule "where an agency merely expresses its view of what the law requires of a party") (internal quotation marks omitted).

To be sure, the SHO Letter represents a change in CMS's *sub*-regulatory practice, as it signals a change in CMS's policy guidance as to what constitutes "reasonable" crowd-out procedures. When CMS originally promulgated 42 C.F.R. § 457.805, it chose not to specify what

substitution prevention mechanisms it would consider "reasonable" above 250% FPL. Rather, CMS noted that it expected its conception of "reasonable procedures" to evolve over time based on emerging research and continuing state experience with substitution. *See* 66 Fed. Reg. 2,603-04. Now, CMS has decided, based on more recent studies and accumulated expertise, that more specific guidance is needed. Thus, for states opting to extend eligibility above 250% FPL, where the risk of substitution is greater, the SHO Letter makes clear what procedures CMS currently considers to be necessary in order to reasonably protect against crowd-out. A change in position of this sort is perfectly permissible given that the underlying regulation at issue is flexible and does not mandate a fixed mode of enforcement. Indeed, the very purpose of a general statement of policy or interpretive rule is to provide notice of how the agency intends to enforce *discretionary* or *ambiguous* legal requirements.[11] An agency's attempt to further clarify its approach to enforcing an existing regulation does not imply that the regulation has been "amended." *See Am. Mining Cong.*, 995 F.2d at 1112 ("A rule does not . . . become an amendment because it supplies crisper and more detailed lines than the authority being interpreted.").

Finally, plaintiffs cannot argue that treating the SHO Letter as a general statement of policy or interpretive rule would allow the agency to obtain the benefits of a legislative rule without incurring the burdens of notice-and-comment rulemaking. *Cf.* Pfs.' Pre-Mot. Conf. Letter at 2 ("If an agency could make binding policy through a rulemaking process that does not entail notice and comment, it would have little incentive to use that more cumbersome process.") (quoting

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[11] *See* Attorney General's Manual on the Administrative Procedure Act 30 n. 3 (defining general statements of policy as "statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power"); *Cen. Tex. Tel. Co-op, Inc. v. FCC*, 402 F.3d 205, 214 (D.C. Cir. 2005) ("[A]n agency may use an interpretive rule to transform a vague statutory duty or right into a sharply delineated duty or right.").

John J. Manning, *Nonlegislative Rules*, 72 GEO. WASH. L. REV. 893, 894 (2004)). As a general statement of policy or interpretive rule, the SHO Letter does not afford the agency the benefits of a legislative rule, because it is not binding law. Again, in any final decision applying the guidance in the letter, the agency must explain how the decision is supported by the statutory and regulatory provisions on which the letter relies. If the agency fails to do so, it risks being reversed on judicial review, because the SHO Letter is not owed the same deference as a legislative rule. *N.Y. City Employees' Retirement Sys.*, 45 F.3d at 14 ("Agency rules that have not undergone notice and comment receive much closer scrutiny from the courts than do those that have cleared the procedural hurdles.").[12] In other words, CMS "must be prepared to support the policy just as if the policy statement had never been issued." *Pac. Gas*, 506 F.2d at 38. Conversely, however, the agency was never required to issue the SHO Letter in the first place; it could have simply developed the policies in the letter through case-by-case adjudication. *See id.* at 41 ("The FPC of course was under no compulsion to issue [the policy statement] . . . . and could have proceeded on an *ad hoc* basis . . . ."). *A fortiori*, the agency was not required to announce the policy through rulemaking proceedings.

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[12] As one commentator has explained, in choosing whether to make policy through legislative rules or policy statements, the agency has a choice between "pay me now, or pay me later": "It can go through the procedural effort of making a legislative rule now and avoid the burdens of case-by-case justification down the road, or it can avoid the hassle of rulemaking now, but at the price of having to engage in more extensive, case-by-case justification down the road. The central point is, however, that this is and should remain the *agency's* choice." E. Donald Elliot, *Re-Inventing Rulemaking*, 41 DUKE L.J. 1490, 1491 (Jun. 1992); *accord* William Funk, *When Is a "Rule" a Regulation? Making a Clear Line Between Nonlegislative Rules and Legislative Rules*, 54 ADMIN L. REV. 659, 665 (Spring 2002).

CONCLUSION

For the foregoing reasons, plaintiffs' complaint should be dismissed in its entirety for lack of jurisdiction. To the extent that the Court reaches plaintiffs' procedural challenge, it should be dismissed for failure to state a claim.

Dated: New York, New York
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